

## **REMARKS**

### **Claims**

Claims 1-8, 10, 11, 45, and 57 are now canceled, without prejudice or disclaimer to their future filing in this, or a related, application. New Claims 58-74 are pending in the application, and are entered largely for the purpose of clarity.

Support for new Claims 58-74 can be found throughout the application as filed, particularly in the originally-filed claims and the prior set of amended claims. The particular ranges of nucleotides and amino acids recited in Claims 58-64 find additional support in the specification at, for example, page 11, lines 1-5; page 42, line 5 - page 43, line 11; Example 3, page 95, lines 9-13; Figures 3A, 3B, and 3C. No new matter has been added by this new claim set. The rejections set forth in the Office Action have been rendered moot by the amendment or are overcome by argument below.

## **THE OFFICE ACTION**

### **1. Maintained Formal Matters, Objections, and/or Rejections.**

A. The Office Action maintained the rejection of Claims 2-8, 10, 11, and 45 under 35 U.S.C. § 112, first paragraph, allegedly for failing to comply with the written description requirement. This basis of rejection was also applied to Claim 57. More specifically, the Office asserted that it is impossible to ascertain the limitations imposed by the term "an activity" used with reference to the polypeptides encoded by the claimed polynucleotides.

The Claims are amended as noted above. Applicants believe this basis of rejection is rendered moot in light of the instant amendments to the claims.

B. The Office Action maintained the rejection of Claims 2-8, 10, 11, and 45 under 35 U.S.C. § 112, first paragraph, allegedly for failing to enable one of skill to make and use the full scope of the claimed invention. This basis of rejection was also applied to Claim 57. More specifically, the Office asserted that it is impossible to enable the full scope of the claims because the limitations imposed by the term "an activity," as well as essential amino acid sequence for producing the activity, are unclear or not disclosed.

The Claims are amended as noted above. Applicants believe this basis of rejection is

rendered moot in light of the instant amendments to the claims.

C. The Office Action maintained the rejection of Claims 2-8, 10, 11, and 45 under 35 U.S.C. § 112, second paragraph, allegedly for failing to particularly point out and distinctly claim the subject matter regarded to be the invention. More specifically, the Office asserted that it is impossible to ascertain the metes and bounds of the term "an activity" when used with reference to the polypeptides encoded by the claimed polynucleotides.

The Claims are amended as noted above. Applicants believe this basis of rejection is rendered moot in light of the instant amendments to the claims.

D. The Office Action maintained the rejection of Claims 3-5, 7, 11, and 45 under 35 U.S.C. § 102(a), alleged to be anticipated by Jacobs (International Patent Application WO 99/57132). In particular Jacobs is alleged to disclose an isolated nucleic acid molecule wherein the isolated nucleic acid molecule comprises a nucleotide sequence encoding at least a 377 amino acid polypeptide wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:8, having a C- and/or N-terminal truncation.

The Claims are amended and encompass, among other things, (a) isolated polynucleotides comprising nucleotides 195-1487, 186-1487, or 132-1487 of SEQ ID NO:7; (b) isolated polynucleotides encoding a polypeptide comprising amino acids 22-452, 18-452, or 1-452 of SEQ ID NO:8; (c) isolated polynucleotides encoding a polypeptide comprising amino acids 22-452 of SEQ ID NO:8, where the polypeptide has an N- or C-terminus truncation, and retains capacity to bind BMP-4.

As argued, in part, in the Response to Office Action, dated September 19, 2003, the nucleic acid molecule disclosed by Jacobs does not comprise SEQ ID NO:7 or encode the polypeptide of SEQ ID NO:8. Jacobs also fails to teach (a) an isolated polynucleotide comprising nucleotides 195-1487, 186-1487, or 132-1487 of SEQ ID NO:7; (b) isolated polynucleotides encoding a polypeptide comprising amino acids 22-452, 18-452, or 1-452 of SEQ ID NO:8; and (c) isolated polynucleotides encoding a polypeptide comprising amino acids 22-452 of SEQ ID NO:8, where the polypeptide has an N- or C-terminus truncation, and retains capacity to bind Bone Morphogenetic Protein-4. Thus, Jacobs fails to teach or suggest the invention, as claimed.

For these reasons, Applicants believe that Jacobs fails to properly anticipate the pending Claims of the invention under 35 U.S.C. § 102(a), and respectfully request reconsideration and

withdrawal of this maintained basis of rejection.

### **New Objections and Rejections**

#### **2. Claim Objections**

Claims 8 and 10 stand objected to under 37 CFR 1.75(c), alleged to be in improper multiple dependent claim format. In light of the amendments to the claims, Applicants believe this objection is moot.

#### **3. Rejection of Claims under 35 U.S.C. § 112, first paragraph**

Claims 2-8, 10, 11, 45, and 57 stand rejected under 35 U.S.C. § 112, first paragraph, alleged to fail the written description requirement. Specifically, the Office asserts that the disclosure lacks support for "377 amino acid residues," "1131 nucleotides," "wherein the residue at position 95...-lysine," and the various species of amino acid substitutions described in Claim 57.

The Claims are amended as discussed above. Applicants cite to support for the pending Claims in the specification in the "Remarks" section above. The new Claims are fully supported by the disclosure as filed. Applicants believe this rejection is moot.

#### **4. Rejections of Claims under 35 U.S.C. § 112, second paragraph**

A. Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph, alleged to be indefinite. Specifically, the Office asserts that the recitation of "the percent identity" lacks antecedent basis.

The amendments to the Claims render this rejection moot.

B. Claims 2, 4-8, 10, 11, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, alleged to be indefinite. Specifically, the Office asserts that the recitation of "wherein the residue at position 95...and the residues at positions 319-323" makes the Claims indefinite because it is unclear whether the residue at position 95, or the residues at positions 319-323 of SEQ ID NO:8 are intended.

The amendments to the Claims render this rejection moot.

C. Claims 3-8, 10, 11, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, alleged to be indefinite for lacking clarity in the language. Particularly, the Office asserts that the

"C- and/or N-terminal truncation" or "at least one modification..." language, combined with the "comprising 377 amino acid residues" language makes the Claims ambiguous and unclear regarding what particular alternative embodiments are intended.

The amendments to the Claims render this rejection moot. As new Claim 64 retains the language "...encodes a polypeptide comprising amino acids 22-452 of SEQ ID NO:8, wherein the polypeptide has an amino- or carboxy-terminus truncation...", Applicants briefly discuss this rejection as if it were applied to Claim 64. The claim language is neither unclear nor ambiguous. The scope of the Claim is apparent to one of skill in the art, particularly when considering it along with Claim 62 ("An isolated polynucleotide that encodes a polypeptide comprising amino acids 22-452 of SEQ ID NO:8."). As Claim 62 encompasses isolated polynucleotides that encode a polypeptide comprising amino acids 22-452 of SEQ ID NO:8, Claim 64 should vary in scope and encompass a different breadth of subject matter. M.P.E.P. § 706.03(k).

D. Claims 2-8, 10, 11, and 45 stand rejected under 35 U.S.C. § 112, second paragraph, alleged to be indefinite for lacking clarity in the language.

The amendments to the Claims render this rejection moot.

## **5. Rejection of claims 3-8, 10, and 45 under 35 U.S.C. § 102(b)**

Claims 3-8, 10, and 45 stand rejected under 35 U.S.C. § 102(b), alleged to be anticipated by DeRobertis (U.S. Patent 5,679,783). Specifically, the Office alleges that DeRobertis discloses an isolated nucleic acid molecule encoding a polypeptide comprising at least 377 amino acid residues and at least a single amino acid of SEQ ID NO:8, operatively linked to expression control sequences other than the native CHL gene promoter, expression vectors, host cells comprising the expression vectors, and a method for producing the polypeptide.

According to MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). 'The identical invention must be shown in as complete detail as is contained in the...claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)."

The Claims are amended as noted above and are, in part, directed to (a) an isolated polynucleotide that comprises nucleotides 195-1487, 186-1487, or 132-1487 of SEQ ID NO:7; and

(b) an isolated polynucleotide that encodes a polypeptide comprising amino acids 22-452, 18-452, or 1-452 of SEQ ID NO:8.

The disclosure of DeRobertis fails to teach or suggest the invention as claimed. De Robertis does not disclose or suggest an isolated polynucleotide that comprises nucleotides 195-1487, 186-1487, or 132-1487 of SEQ ID NO:7; or (b) an isolated polynucleotide that encodes a polypeptide comprising amino acids 22-452, 18-452, or 1-452 of SEQ ID NO:8, as recited in the pending Claims. DeRobertis merely describes the full length *Xenopus* cDNA chordin sequence, and the encoded polypeptide. Accordingly DeRobertis fails to teach or suggest the claimed polynucleotides of the invention, expression vectors comprising those polynucleotides, host cells comprising the expression vectors, polynucleotides that are complementary to the claimed polynucleotides, and a process for producing a CHL polypeptide comprising the host cells. Thus, DeRobertis fails to anticipate the pending claims.

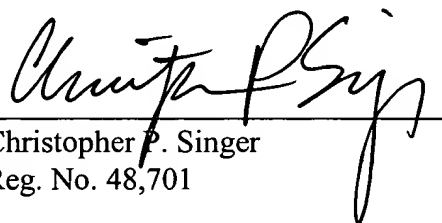
Applicants respectfully contend that this rejection based on 35 U.S.C. § 102(b) has been rendered moot by amendment or overcome by argument, and respectfully request that the Examiner reconsider and withdraw the rejection made on this basis.

### **CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

Respectfully submitted,  
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